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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,844	08/06/2001	Shujath M. Ali	DEX-0176	7509

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,844	ALI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,13-15,17-19,21,23,24 and 26-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,13-15,17-19,21,23,24 and 26-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 8, 9, 13-15, 17-19, and 21, 23, 24, and 26- 45 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of objection to the claims.

Claim Objection, Maintained

Since claims 13, 17, 21 depend on claims 8, 14, and 18 respectively reciting "the native protein encoded by SEQ ID NO: 1". The claims as construed say that "the native protein encoded by SEQ ID NO: 1 is amino acids 14 to 327 of SEQ ID NO: 2. Therefore, the scope is identical, thus not further limiting the base claims. Objection of other claims not repeated here is withdrawn.

Claim Rejections - 35 USC § 112, Maintained

Claims 8, 9, 13-15, 17-19, and 21, 23, 24, 26- 45 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reason of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention is drawn to a method of imaging of a gynecologic cancer using an monoclonal or polyclonal antibody which specifically binds to SEQ ID NO: 2 (claims 8, 13), wherein said antibody is labeled (claim 9), or method of delivering a derivatized antibody (the specification at page 7 line 14, appears to limit "derivatized"

as attaching cytotoxic agent or other art-known agents to an antibody that binds to SEQ ID NO: 2), which specifically binds to SEQ ID NO:2, to a gynecologic cancer cell in vivo (claims 14, 15, 17), or delivering said derivatized antibody to a gynecologic tumor in vivo (Claims 18, 19, 21), wherein new claims 22-27 characterizes that the protein of the base claims to be protease with active domains, or SEQ ID NO:2, wherein the new claims 28-45 specifies various gynecologic cancer.

Applicant argues that SEQ ID NO:2 of the instant application is a polypeptide containing the deduced amino acid sequence of the polynucleotide SEQ ID NO:I and depicts in its sequence 13 amino acids before the initial methionine of the native protein encoded by SEQ ID NO:I. These 13 deduced amino acids depicted in SEQ ID NO:2 occur prior to the translation initiation codon and thus do not occur in the native protein encoded by SEQ ID NO:I. Comparison of the native protein encoded by SEQ ID NO:I, depicted in SEQ ID NO:2 from the first methionine at amino acid position 14 to position 327, with testisin shows the proteins to be identical. Applicant also argues that one of skill in the art would have known how to search ORF of a given gene before the effective filing date of the instant application given many papers about the subject matter have been published before the effective filing date of the instant application as shown in the supplemental IDS filed on 07/17/2006.

These arguments have been fully considered but found unpersuasive because applicant argues with a disclosure not presented in the specification as originally filed. The specification at page 4 lines 27 to 30 discloses that "native protein expressed by the gene comprising the polynucleotide sequence of SEQ ID NO: 1. The amino acid

sequence of a polypeptide encoded by SEQ ID NO: 1 is depicted herein as SEQ ID NO: 2." The specification as originally filed does not disclose that a polypeptide comprising amino acids 14 to 327 of SEQ ID NO:2 is the native protein, as applicant now argues.

Applicant's arguments and data shown in the poster presentation of Papkoff et al., and the post-filing publication of Tang et al., have been fully considered, but unpersuasive for the following reasons. First, during the prosecution history, the limitation "Pro104" in the instant claims is determined to be limited to the instant SEQ ID NO: 2 protein. See the Office action mailed on 04/21/2004, and applicant's subsequent response, as well as the interpretation of the claims. The specification as originally filed does not reasonably communicates that the protein known in the art, as "testisin" is same as the instantly claimed Pro104. The attached sequence alignment aligning the instant SEQ ID NO: 2 against what is the protein known as testisin in the art (Exhibit A) demonstrate that instant SEQ ID NO: 2 is not same as testisin. Therefore, the argument with Tang et al., is not germane to the instantly claimed invention.

As for argument with Papkoff et al., Papkoff et al., discloses the Pro104 is over-expressed in ovarian cancer. However, Papkoff et al., do not establish whether Pro104 is same as the instant SEQ ID NO:2. In fact, one of the figure in the poster, top in the 2nd column appears to indicate that Pro104 in Papkoff et al., is testisin, not instant SEQ ID NO:2. In addition, Papkoff et al., do not establish that whether one could image gynecologic cancers using polyclonal or monoclonal antibody specifically binding to the instant SEQ ID NO:2 encoded by instant SEQ ID NO:1. Papkoff et al., teach that

detection of overexpression of Pro104 (testisin) in ovarian cancer tissue samples as compared to normal ovarian tissue.

As stated before in the two previous Office actions, Aloj et al., (2002, Biopolymers. Vol. 66, pages 370-80) teach that in order to target specific molecules inside the body using radiopharmaceuticals such as a radioisotope-labeled antibody, several parameters have to be considered: (1) the target protein should be over-expressed in cancer to be imaged; (2) a radiopharmaceutical should be tested to see whether said radiopharmaceutical specifically binds to the in vivo target *in vivo*; (3) how the unbound radiopharmaceutical is cleared for minimizing unwanted high background (note the abstract, and pages 372-373). The instant specification has failed to teach with a reasonable certainty that the protein encoded by SEQ ID NO:1 is a gynecologic cancer antigen while the art (see Hooper et al., above) suggests that the protein encoded by SEQ ID NO:1 is a tumor suppressor. Low et al., (1995, Radiology, vol. 195, pages 391-400) also teach that in order to image an ovarian cancer (a species of a gynecologic cancer), selection of an antibody that specially binds to an ovarian cancer-associated antigen, is the first necessary step (see page 391 middle column; the authors selected an antibody targeting Tag-72, a previously known ovarian cancer antigen). Low et al., further teach accuracy of imaging using an antibody directed to a cancer antigen has to be evaluated against other known cancer detection methods such as histology or pathology (note page 393 under the heading "Pathologic Proof", and Table 3 at page 396). Likewise, Krag et al., (1993, Arch. Surg. Vol. 128, pages 819-23) teach method of imaging an ovarian cancer using a radio-labeled (i.e. indium 111-

labeled) CYT-103 monoclonal antibody requires selection of an antibody capable of binding to an antigen that is over-expressed in an ovarian cancer (see page 820 under the heading "Patients, Materials, and Methods").

Considering the unpredictable state of art, limited guidance, no examples in the specification how to use the instantly claimed invention, broad breath of the claims, it is concluded that undue experimentation is required to practice the invention.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 8, 9, 13-15, 17-19, and 21, 23, 24, 26- 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The claims as currently amended say that the native protein comprises amino acids 14 to 327 of SEQ ID NO:2. However, the specification at page 4 lines 27 to 30 discloses that "native protein expressed by the gene comprising the polynucleotide sequence of SEQ ID NO: 1. The amino acid sequence of a polypeptide encoded by SEQ ID NO: 1 is depicted herein as SEQ ID NO: 2."

The specification as originally filed does not disclose that a polypeptide comprising amino acids 14 to 327 of SEQ ID NO:2 is the native protein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642